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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,492	03/06/2002	Elizabeth S. Light	142/003/PCT	8768

23874 7590 10/16/2006

VENTANA MEDICAL SYSTEMS, INC.  
ATTENTION: LEGAL DEPARTMENT  
1910 INNOVATION PARK DRIVE  
TUCSON, AZ 85755

EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/582,492

Applicant(s)

LIGHT ET AL.

Examiner

Juliet C. Switzer

Art Unit

1634

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 3, 7, 17, 19, 22.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Continuation of 3. NOTE: (a) The newly added claims provide new issues for search and consideration. First, claim 23 requires decreased relative proportions of HPV probes of different types. There was no such claim previously provided, and the search and consideration of such limitations would be a new issue. Further, claim 24 raises new issues for search as this claim requires that certain fragments are removed under particular wash conditions that were not previously set forth in the claims. Also, the claim raises new issue under 112 2nd because the dependent claim sets forth that fragments "are removed" and appears to be a method step, but the claim is a product claim. It is not clear how the method limitations apply to the product claim. The product claim does not require that the claimed reagents are hybridized to a cell sample, the independent claim merely sets forth properties regarding what the reagent would detectably hybridize to. (b) New claim 25 raises the issue of new matter because while there is clear basis for a probe reagent set in which particular relative concentrations of probe types are present there is a question as to whether there is clear basis for the broader claim recited in the amendments describing general relative proportions. Further, applicant does not cite basis for claim 24 which recites new wash conditions and so the issue of new matter is also raised relative to these claims. (c) Since the newly filed amendments raise new issues under (a) and (b) above, the amendments are not deemed to place the application in better form for appeal since new issues would have to be addressed.

Regarding number 8 above, the declaration is not timely filed because it is not drawn to address issues which were raised SOLELY in the FINAL rejection. The rejection under Nuovo in view of Cox was not first entered in the final rejection.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the rejection under Nuovo et al. should be withdrawn as it does not provide enabling disclosure regarding the contents of the consensus probe mix. However, this is not persuasive. The disclosure of the Nuovo et al reference teaches that the consensus probe contains multiple high HPV types (p. 160) and the hybridization profile of the probe (that is which types the consensus probe hybridized to and which it did not). At the time the invention was made, it was routine to optimize probe concentrations in order to determine optimal concentrations of probes, this issue has been previously addressed in the prosecution history of this application. Thus, given the disclosure of Nuovo et al., there is enabling disclosure for the production of the claimed probe set. Further, it is noted that this rejection is not applied to claims which recite the particular concentrations of the probe sets, as Nuovo et al. do not provide sufficient disclosure to meet such a claim. The rejected claims require only particular functions of the probe set and Nuovo et al. provide these. This rejection is maintained against the pending claims. The declaration was not considered because the declaration itself is inclusive of arguments against a rejection that was first applied in the final rejection.

Applicant's remarks regarding the declaration to overcome the 103 rejections have not been considered as this declaration is not timely filed in the after-final submission. Further, regarding the arguments that the references do not disclose the specific proportions of the probes, it is noted that claims 1 and 3 do not require these proportions. If applicant suggests that these proportions are the only means to arrive at an operable invention, applicant should consider whether these proportions are an essential feature of the claimed invention. Applicant's remaining arguments regarding this rejection have been addressed in previous office actions.



**JULIET C. SWITZER**  
**PRIMARY EXAMINER**